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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/700,767 | 11/04/2003 | Andrew Thomas Forsberg | 47563.0009 | 6326 |
| 57600 | 7590 | 06/15/2006 | | |
| HOLLAND & HART LLP 60 E. SOUTH TEMPLE SUITE 2000 SALT LAKE CITY, UT 84111 | | | EXAMINER POUS, NATALIE R | |
| | | | ART UNIT 3731 | PAPER NUMBER |

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/700,767

Applicant(s)

FORSBERG ET AL.

Examiner

Natalie Pous

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 22-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/4/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claims 22-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/24/06.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The word "invention" should be avoided in the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1, is rejected under 35 U.S.C. 102(e) as being anticipated by Dodge (US 6802822)

Regarding claim 1, Dodge teaches a puncture closure assembly, comprising: a tissue puncture closure device (42) having a distal and a proximal end; a vascular insertion sheath (10, 18, 20) wherein the distal end of the insertion sheath (20) comprises a tip portion (20) that is stiffer than the insertion sheath portions adjacent to the tip portion (18).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4, 5 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. (US 5861004) in view of Bogert et al. (US 6096012).

Kensey teaches a puncture closure assembly, comprising the following:

- a tissue puncture closure device (22) having a distal and a proximal end
- a vascular insertion sheath (28) wherein the distal end of the insertion sheath (28c) comprises a tip portion
- a filament (34) extending from the proximal end of the closure device to the distal end of the closure device

Art Unit: 3731

- an anchor (32) for insertion through a tissue wall puncher attached to the filament at the distal end of the closure device (fig. 1)
- a sealing plug (30) slidably disposed about the filament at the distal end of the closure device (fig. 1).

Kensey fails to disclose the following:

- wherein the tip portion is stiffer than the insertion sheath portions adjacent to the tip portion
- wherein the stiffer tip portion comprises a second layer of material wherein the wall thickness is greater at the tip portion than at the portion adjacent to the top portion

Bogart teaches an insertion sheath wherein the distal tip portion is stiffer than the insertion sheath portions adjacent to the tip portion wherein the stiffer tip portion comprises a second layer of material making the tip portion thicker than the rest of the sheath in order to enable insertion into the body of the patient (Column 3, proximate lines 30-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kensey with a stiffer tip portion as taught by Bogart in order to enable insertion of the sheath into the body of the patient.

Claims 1, 2, 3, 8, 9, 13, 14, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. (US 5861004) in view of Buck et al. (US 6270470).

Kensey teaches a puncture closure assembly, comprising the following:

- a tissue puncture closure device (22) having a distal and a proximal end

Art Unit: 3731

- a vascular insertion sheath (28) wherein the distal end of the insertion sheath (28c) comprises a tip portion
- a filament (34) extending from the proximal end of the closure device to the distal end of the closure device
- an anchor (32) for insertion through a tissue wall puncher attached to the filament at the distal end of the closure device (fig. 1)
- a sealing plug (30) slidably disposed about the filament at the distal end of the closure device (fig. 1).
- A hemostatic valve (28a) coupled to the proximal end of the tubular member (fig. 13)

Kensey fails to disclose the following:

- wherein the tip portion is stiffer than the insertion sheath portions adjacent to the tip portion
- wherein the stiffer tip portion comprises a concave fold
- wherein the concave fold comprises no more than half of a circumference of the insertion sheath
- the stiffer tip portion comprises at least one stiffening ridge
- the stiffer tip portion comprises at least 2 stiffening ridges
- at least a portion of the fold comprises a thicker wall at the edge of the fold than the flexible tubular member

Buck teaches an insertion sheath (22) wherein the tip portion (24) is stiffer than the insertion sheath portions adjacent to the tip portion wherein the stiffer tip portion

comprises a concave fold (fig. 7), wherein the concave fold is comprises no more than half of a circumference of the insertion sheath (fig. 6a), the stiffer tip portion comprises at least one stiffening ridge (32), the stiffer tip portion comprises at least 2 stiffening ridges (30, fig. 10), at least a portion of the fold comprises a thicker wall than the flexible tubular member (32) at the edge of the fold (fig. 4) in order to guide the sealing plug out of the sheath and into the body. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kensey with areas of increased stiffness as taught by Buck in order to guide the sealing plug out of the sheath and into the body.

Claims 5-7 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kensey and Buck as applied to claim 1 above, and further in view of Bogart. The combination of Kensey and Buck teaches all limitations of preceding dependent claim 1 and further teaches a concave fold along the tip portion. The combination of Kensey and Buck fails to disclose wherein a second layer of material is disposed along the edge of the concave fold. Bogart teaches a vascular insertion sheath comprising a second layer of material (28) disposed along the edge of the tip of the sheath in order to enable insertion into the body of the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Kensey and Buck with a second layer of material as taught by Bogart in order to enable insertion into the body of the patient.

Claims 10-12 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kensey and Buck as applied to claim 1 above,

and further as a matter of design choice. Since the applicant has not disclosed that providing orthogonal ridges or a transverse corrugated section provides any advantage over longitudinal ridges, and it appears that the combination of Kensey and Buck performs the task of guiding the sealing device out of the sheath and inhibiting re-entry of the device equally well as that disclosed in the application, it would have been an obvious matter of design choice to modify the combination of Kensey and Buck with transverse ridges or corrugations.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
6/6/06



(JACKIE) TAN-LYEN HO
PRIMARY EXAMINER
6/9/06